Add new claims 43 and 44 that read as follows:

43. (NEW) An imaging system for invasive therapy of a patient, the system comprising:
an imaging apparatus that can provide a cross-sectional image of a patient;

a medical instrument comprising a fiducial object that can be imaged in the same image as a targeted site of the patient; and

wherein the fiducial object comprises three N-shaped fiducial motifs, and the three N-shaped fiducial motifs are non-coplanar.

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44. (NEW) A method for guiding invasive therapy in a patient, comprising:

a) providing a system that comprises an imaging apparatus and a medical instrument comprising a fiducial object that can be imaged in the same image as a targeted site of the patient, the fiducial object including three N-shaped fiducial motifs, where the three fiducial motifs are non-coplanar;

b) obtaining a cross-sectional image that comprises both the fiducial object and the targeted site of the patient; and

c) manipulating the instrument with respect to the patient using information derived from the image.

REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 1-42 are pending in the subject application. Claims 1-7, 10, 13-21, 30-34, 37 and 39-42 stand rejected under 35 U.S.C. §102. Claims 8, 9, 11, 12, 22-29, 35, 36 and 38 were

objected to as depending from a rejected base claim, however, the Examiner indicated that the claims would be allowable if appropriately re-written in independent form.

Claims 1, 16, 40, 41 and 42 were amended as suggested by the Examiner. Added claims 42 and 43 comprise a re-presentation of objected to claims 8 and 35 re-written so as to be in independent form. Thus, additional search or examination of added claims 42 and 43 is not required, and therefore entry of these added claims is respectfully requested. Claim 11 was amended for consistency of language amongst the claims. The amendments to the claims are supported by the originally filed disclosure.

Included herewith is a marked-up version of the amendments to the subject application by the current amendment. The marked-up versions are found on the pages captioned or entitled "Details of Amendments" that follow the signature page of the within Response.

35 U.S.C. §102 REJECTIONS

Claims 1-7, 10, 13-21, 30-34, 37 and 39-42 stand rejected under 35 U.S.C. §102(b) as being anticipated by Dumoulin [USP 5,318,025]. Applicants respectfully traverse as discussed below.

The above-referenced Office Action asserts that Dumoulin discloses a tracking system to monitor the position and orientation of a device such as catheter by using magnetic resonance detection. It also is asserted that the flexible device in Dumoulin contains intermediate sensors and a sensor proximate the distal tip, where the sensors are RF coils that detect MR signals that

are generated in response to a controlled 3-dimensional magnetic field generated by a set of gradient coils. It is further asserted that these RF coils in combination with the disclosed processing and calculating means provide identifiable points for all of the coils and the unique orientation of the device within its range of motion.

As to Applicants' prior arguments, the above-referenced Office Action also states that the term imaging is simply the action or process of producing an image. The Office Action also states that this term does not automatically imply that all elements are acquired simultaneously but rather the term image means that an image containing all elements is produced. Thus, and because the express language of the claims is not expressly limited to simultaneous or at the same time acquisition of image data, it appears that the phrase "imaged in the same image as the targeted site" is being interpreted in the Office Action to mean no more that the action or process of forming any image, including that imaging process described in Dumoulin.

Although, Applicants believe that the claims once read in light of the specification of the present invention would apprise one skilled in the art as to the scope of the claimed invention and that the claims are distinguishable from the cited reference, Applicants have amended the pending independent claims in view of the Examiner's suggestion to expressly indicate in the claims that the medical instrument and the target site are being imaged at the same time. In other words, the image data being acquired includes the fiducial object included with the medical instrument *and* the targeted tissues, etc. of the patient.

This express limitation, however, *shall not* be construed as meaning or suggesting that all

elements of the area being imaged are acquired in a manner different from that done in accordance with the imaging process. For example, and as is known by those skilled in the art, NMR/ MR imaging is accomplished by imaging or scanning slices of the area being imaged and then reconstructing these slices to produce a complete image. Using this example, it should be understood that the express limitation being added to the claims does not mean that the NMR/MR imaging process is performed differently (for example, the limitation *does not* mean or suggest that all slices are acquired at the same time).

Thus, Applicants again adopt herein the prior remarks (see Applicants' Response dated December 10, 2002), that Dumoulin does not disclose the tracking system and methodology as claimed by Applicants. As had been previously indicated, and is known to those skilled in the art, Dumoulin describes and teaches a tracking technique whereby a short series of RF and gradient pulses are used to locate the RF coils/sensors. This tracking process/ technique does *not* involve generating an image nor generating a cross-sectional image of the targeted site of the subject. In Dumoulin, a cross-sectional image is acquired using any one of the enumerated techniques disclosed therein, including the MRI technique, in an entirely separate step from that involved with the tracking process. The location of this cross-sectional image presumably is chosen based on the determined location of the RF coils/sensors. Thus, in Dumoulin, any cross-sectional images generated using any of the enumerated imaging techniques disclosed therein provide no information as to the location of the device within the subject.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set

forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks and those contained in Applicants' Response dated December 10, 2002, the above-identified claims are not anticipated by Dumoulin. It also is respectfully submitted that these remarks also make clear that there is Dumoulin does not provide any teaching nor suggestion of the claimed invention. It is further submitted, that there is no teaching, suggestion nor any motivation offered in Dumoulin for modifying the imaging system or methodology described therein so as to yield the imaging system or the methodology as set forth in any of the claims of the present invention.

It is respectfully submitted that for the foregoing reasons, claims 1-7, 10, 13-21, 30-34, 37 and 39-42 are patentable over the Dumoulin and satisfy the requirements of 35 U.S.C. §102(b). As such, these claims, including the claims dependent therefrom are allowable.

CLAIMS 8, 9, 11, 12, 22-29, 35, 36 & 38

In the above-referenced Office Action, claims 8, 9, 11, 12, 22-29, 35, 36 and 38 were objected to as being dependent upon a rejected base claim. It also was provided in the above-

referenced Office Action, however, that these claims would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claim(s).

In as much as Applicants believe that the base claims for each of claims 8, 9, 11, 12, 22-29, 35, 36 and 38 are in allowable form, these claims were not re-written in independent form as suggested by the Examiner. As to claim 8 and 35, however, Applicants have presented added independent claims 43 and 44 that were written so as to include the limitations respectively of claims 8 and 35 and the associated related base claim (there being no intervening claims). Applicants, however, reserve the right to later amend the subject application so as to present any one or more of claims 9, 11, 12, 22-29, 36 and 38 in independent form or to add one or more independent claims that contain the limitations of any one or more of these claims.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Because the total number of claims and/or the total number of independent claims in the subject application post amendment now exceed the highest number previously paid for, a check is enclosed herewith for the required additional fees. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,
Edwards & Angell, LLP

Date: July 2, 2003

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DETAILS OF AMENDMENTS

Please amend the subject application as follows:

IN THE CLAIMS

Amend claims 1, 11, 16, 40, 41 and 42 to read as follows:

1. (AMENDED) An imaging system for invasive therapy of a patient, the system comprising:

an imaging apparatus that can provide a cross-sectional image of a patient;

a medical instrument comprising a fiducial object that can be simultaneously imaged in the same image as a targeted site of the patient.

11. (TWICE AMENDED) The system of any one of claims 1 through 10 wherein the system further comprises a robotic apparatus capable of positioning the ~~apparatus~~ medical instrument.

16. (AMENDED) A method for guiding invasive therapy in a patient, comprising:

a) providing a system that comprises an imaging apparatus and a medical instrument comprising a fiducial object that can be simultaneously imaged in the same image as a targeted site of the patient;

b) obtaining a cross-sectional image that comprises both the fiducial object and the targeted site of the patient; and

c) manipulating the instrument with respect to the patient using information derived from the image.

40. (AMENDED) An imaging system for invasive therapy of a patient, the system comprising:

an imaging apparatus that can provide a cross-sectional image of a patient;

a medical instrument comprising a fiducial object that can be simultaneously imaged in the same cross-sectional image as a targeted site of the patient, the image producing three identifiable points to coordinate pose of the instrument and the targeted site of the patient; and

a control apparatus that can register the instrument in detected image space and calculate instrument movement.

41. (AMENDED) A method for guiding invasive therapy in a patient, comprising:

a) providing a system that comprises i) an imaging apparatus, ii) a medical instrument comprising an associated fiducial object that can be simultaneously imaged in the same cross-sectional image as a targeted site of the patient, and iii) a control apparatus that can, via input from the imaging apparatus, register the instrument in detected image space and calculate instrument movement;

b) obtaining a cross-sectional image that comprises both the fiducial object and the targeted site of the patient, the image producing three identifiable points to coordinate pose of the instrument and the targeted site of the patient; and

c) based on input from the control apparatus, manipulating the instrument with respect to the patient using information derived from the image.

42. (AMENDED) A method for guiding invasive therapy in a patient, comprising:

a) providing a system that comprises i) an imaging apparatus, ii) a medical instrument comprising an associated fiducial object that can be simultaneously imaged in the same cross-sectional image as a targeted site of the patient;

b) obtaining a cross-sectional image that comprises both the fiducial object and the targeted site of the patient, a single image providing information sufficient to coordinate pose of

the instrument and the targeted site of the patient; and

c) manipulating the instrument with respect to the patient using information derived from a single cross-sectional image.

Add new claims 43 and 44 that read as follows:

43. (NEW) An imaging system for invasive therapy of a patient, the system comprising:
an imaging apparatus that can provide a cross-sectional image of a patient;

a medical instrument comprising a fiducial object that can be imaged in the same image as a targeted site of the patient; and

wherein the fiducial object comprises three N-shaped fiducial motifs, and the three N-shaped fiducial motifs are non-coplanar.

44. (NEW) A method for guiding invasive therapy in a patient, comprising:

a) providing a system that comprises an imaging apparatus and a medical instrument comprising a fiducial object that can be imaged in the same image as a targeted site of the patient, the fiducial object including three N-shaped fiducial motifs, where the three fiducial motifs are non-coplanar;

b) obtaining a cross-sectional image that comprises both the fiducial object and the targeted site of the patient; and

c) manipulating the instrument with respect to the patient using information derived from the image.